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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/584,482

03/02/2007

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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

01/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,482	Applicant(s) HAGIWARA ET AL.	
	Examiner Jane Zara	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-28, 32 and 33 is/are rejected.
- 7) ☒ Claim(s) 29-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the communication filed 10-7-08.

Claims 24-33 are pending in the instant application.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Player et al (WO 2004/096795) and Nakagawa et al (USPN 5,707,987), the combination in view of Schubert et al (US 2006/0094081) for the reasons of record set forth in the Office action mailed 7-11-08.

Applicant's arguments filed 10-7-08 have been fully considered but they are not persuasive. Applicant argues that Schubert does not teach the treatment of viral infections listed in claims 27, 29-31 because Schubert teaches that only infections with HIV produce high levels of M-CSF and these claims do not encompass the treatment of HIV infections using the instantly claimed compounds.

Claims 24-26, however, are broadly drawn to treating any viral infections, including HIV infections, and claim 28 is drawn to treating HIV, and so the instant obviousness rejection is properly maintained for claims 24-26, and 28. Applicant is correct that Schubert explicitly teaches the targeting of M-CSF as a strategy for inhibiting the spread of HIV. Schubert also teaches that scavenging agents of M-CSF have been found to inhibit HIV replication. These teachings provide a reasonable expectation of success for treating HIV viral infections, as well as HTLV infections, since both viruses were well known to infect macrophages in the presence of M-CSF (see, e.g., Gendelman et al, AIDS, Vol. 4, pages 221-228, 1990, esp. at pages 221-222, 226-227).

For these reasons the instant rejection is maintained.

Rejections Necessitated by Amendment

Claims 27, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Player et al (WO 2004/096795) and Nakagawa et al (USPN 5,707,987), the combination in view of Gendelman et al (AIDS, Vol. 4, No. 2, pages 221-228, 1990).

The claims are drawn to a method of treating a viral infection in a subject comprising the administration of an aniline derivative represented by formula I or II in claim 24, wherein the X is optionally F, Cl, Br, I or At.

Player et al (WO 2004/096795) teach the aniline derivatives represented by the formulae listed in claim 24, pharmaceutically acceptable salts and hydrates thereof, and their ability to inhibit M-CSF kinase (see the text and structures I-III in the abstract; pages 3-17, Table I, pages 33-41, claims 1-18).

Nakagawa et al (USPN 5,707,987) teach aniline derivatives represented by the formulae listed in claim 24, pharmaceutically acceptable salts or hydrates thereof (see esp. the abstract, col. 1-27, 189-190, claims 1-27).

The primary references of Player and Nakagawa do not teach the role of M-CSF in viral infections.

Gendelman et al (AIDS, Vol. 4, No. 2, pages 221-228, 1990) teach the role of M-CSF in the persistence of HIV and HTLV infections. Gendelman teaches that HIV and HTLV viruses infect macrophages, and the unique features imparted to these retroviral-macrophage interactions then allow the viruses to persist as productive infections, despite a vigorous host immune response. "Macrophages act as a nidus of infection virions in many tissues, a nidus that can release virus to infect other HIV-susceptible cells." (bridging paragraph, pages 221-222) (See the text at pages 221-222, 226-227).

It would have been obvious to use the well known aniline derivatives taught previously by Player and Nakagawa to inhibit M-CSF because Player teaches the inhibition of M-CSF kinase using the instantly claimed aniline compounds. One of ordinary skill in the art would have been motivated to inhibit M-CSF kinase as a treatment for viral infections because Gendelman, as early as 1990, teaches the routine use of M-CSF for cultivating the infection of macrophages by various strains of HTLV and HIV, in the presence of M-CSF.

One of ordinary skill in the art would have reasonably expected that inhibiting M-CSF kinase using these well known inhibitors taught previously by Player and Nakagawa would inhibit HIV and HTLV infections of macrophages, which require the presence of functional M-CSF for infection. Furthermore, the testing of these well known inhibitors taught previously by Player and Nakagawa for their ability to inhibit HIV and HTLV viruses would have involved routine experimentation, as taught previously by Gendelman.

For these reasons, the instant invention would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. ' 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jane Zara whose telephone number is (571) 272-0765. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz, can be reached on (571) 272-0763. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jane Zara
1-15-09

/Jane Zara/

Primary Examiner, Art Unit 1635